510(K) SUMMARY

JUN 0 7 2013

11.1 SUBMITTER INFORMATION

A.	Company Name:	Access Scientific, LLC.
B.	Company Address:	3910 Sorrento Valley Boulevard, Suite 200 San Diego, CA 92121
C.	Company Phone:	(858) 259-8333
D.	Company Facsimile:	(858) 259-5298
E.	Contact Person:	Albert Misajon Chief Compliance Officer amisajon@the-wand.com
F.	Date Summary Prepared:	May 6, 2013

11.2 DEVICE IDENTIFICATION

A.	Device Trade Name:	the POWERWAND® Safety Introducer with an Extended Dwell Catheter
B.	Common Name:	Catheter Introducer Intravascular Catheter, Therapeutic, Short-term
C.	Classification Name(s):	Introducer, Catheter
D.	Classification Regulation(s):	21 CFR 870.1340
E.	Device Class:	Class II
F.	Product Code:	DYB
G.	Advisory Panel:	Cardiovascular

11.3 IDENTIFICATION OF PREDICATE DEVICE

The predicate device is the POWERWAND® Safety Introducer with an Extended Dwell Catheter (5 Fr Model and 4 Fr Models) cleared for commercial distribution under Premarket Notification Numbers K111417 and K121748.

11.4 DEVICE DESCRIPTION

The POWERWAND® Safety Introducer with an Extended Dwell Catheter is an all-in-one preassembled intravascular catheter introducer with intravascular catheter that consists of the following basic components: Introducer Needle, Nitinol Guidewire, Dilator and an Extended Dwell Catheter. It is intended to provide the clinician with a safe, simple and accelerated approach, using the Accelerated Seldinger Technique, to place an in-dwelling intravascular catheter through the skin into the circulatory system. The Extended Dwell Catheter allows for withdrawal of blood and the administration of fluids, including power injection of

contrast media. The device also incorporates a mechanism that provides passive needle stick safety.

11.5 INDICATIONS FOR USE

The POWERWAND® Safety Introducer with an Extended Dwell Catheter is used to gain access to the vascular system to sample blood and administer fluids intravenously. May be used for power injection of contrast media at a rate of 5 ml/sec at up to 300 psi fluid pressure.

11.6 TECHNOLOGICAL CHARACTERISTICS

The proposed modified device has the same technological characteristics as the predicate device in terms of components, materials, chemical composition, and design. The changes to the device impact the material of the female Luer hub on the IV Catheter, which has been changed from Pellathane® (polyurethane) to Makrolon® (polycarbonate). Performance testing has been conducted to confirm that the modified device satisfies performance requirements.

11.7 SUMMARY OF TESTING

Design verification testing was conducted to demonstrate that the performance characteristics of the modified POWERWAND® Safety Introducer with an Extended Dwell Catheter (Makrolon Model) is equivalent to the predicate device and satisfy the requirements of the product design specification for its intended use.

The testing conducted for the POWERWAND® with IV Catheter with Makrolon® Hub is shown in **Table 11.1.**

TABLE 11.1: PROSPECTIVE TESTING OF THE POWERWAND®

Component	Testing
IV Catheter with Makrolon® Luer Hub	Biocompatibility testing in accordance with ISO 10993-1:2009
IV Catheter with Makrolon® Luer Hub – Standard Performance Testing	• Tensile Strength • Burst Pressure • Hub Gauging • Leakage Test – Liquid • Leakage Test – Air • Air Leakage during Aspiration • Hub Separation Force • Hub Unscrewing Force • Hub Ease of Assembly • Hub Resistance to Overriding • Hub Stress Cracking • Strain Relief Cover Tensile Test • Strain Relief Cover Flex Test
IV Catheter with Makrolon® Luer Hub – Testing after Pre-Conditioning	• Visual Inspection • Burst Pressure
Introducer System	• Dilator Hub to Catheter Hub Removal Torque • Dilator Hub to Catheter Hub Separation Force • Needle Cover Removal Force

11.8 CONCLUSIONS DRAWN FROM STUDIES

The results of testing demonstrate that the modified POWERWAND® Safety Introducer with an Extended Dwell Catheter (IV Catheter with Makrolon® Luer Hub) is substantially equivalent to the predicate device in design, function, and indications for use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-002

June 7, 2013

Access Scientific, LLC
C/O Albert Misajon
3910 Sorrento Valley Blvd Ste 200
San Diego, CA 92121 US

Re: K131300
Trade/Device Name: POWERWAND® Safety Introducer with an Extended Dwell Catheter
Regulation Number: 21 CFR 870.1340
Regulation Name: Catheter Introducer Intravascular Catheter, Therapeutic, Short-Term
Regulatory Class: Class II
Product Code: DYB
Dated: May 8, 2013
Received: May 9, 2013

Dear Mr. Misajon:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Matthew G. Hillebrenner

for

Bram D. Zuckerman, Ph.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K131300

Device Name: **the POWERWAND® Safety Introducer with an Extended Dwell Catheter**

Indications for Use:

The POWERWAND® Safety Introducer with an Extended Dwell Catheter is used to gain access to the vascular system to sample blood and administer fluids intravenously. May be used for power injection of contrast media at a rate of 5 ml/sec at up to 300 psi fluid pressure.

Prescription Use __X_____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Matthew G Hillebrenner